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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/661,361

09/12/2003

David A. Mackiewicz

ENDOS 64949 (4164P)

6762

24201 7590 05/06/2009  
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EXAMINER

HOUSTON, ELIZABETH

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

05/06/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/661,361	<b>Applicant(s)</b> MACKIEWICZ ET AL.	
	<b>Examiner</b> ELIZABETH HOUSTON	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-15,17,18,21,32 and 41-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-15,17,18,21,32 and 41-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Specification***

The amendment to the specification submitted on 02/13/09 has been accepted.

### ***Claim Rejections - 35 USC § 103***

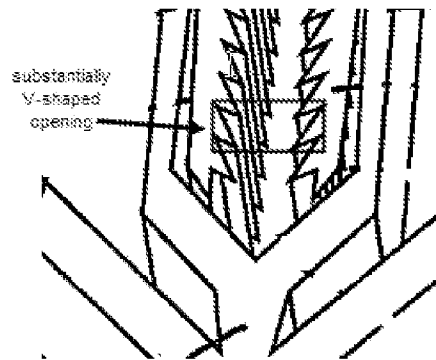
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-4, 6, 7, 32, 42, 51, 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frantzen (USPN 5,741,327) in view of Ehrfeld (DE 197 28 337).
2. Frantzen discloses a stent comprising a structural body having a certain level of radiopacity (nitinol) and at least one marker holder integrally formed therein (For example Fig. 11, 64, 67). The device comprises a radiopaque marker (96) attachable within the marker holder. The marker holder includes a pair of projecting fingers, which define an opening (62). The radiopaque marker (94) includes a mounting region (96) that fits within the opening defined by the fingers. The marker is attached to the fingers by a heat weld (Col 7, L64).
3. Frantzen does not disclose that the projecting fingers have a substantially linearly extending contact edge and forms a V-shaped opening or that the radiopaque marker includes a V-shaped mounting region with linearly extending contact edges.

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4. However Ehrfeld teaches a connecting configuration (Fig. 4a and 4b) with the holder having projecting fingers (26,27) defining a v-shaped opening (for example 24a and 22a) (note that each pair of corresponding ratchets defines a substantially V-shaped opening as best seen in Fig. 4b and for example shown below) and a prong (21) (equivalent of the claimed marker) including a substantially V-shaped mounting region which fits within the opening of the projecting fingers (Fig. 4b). The connecting fingers are connected at a notched region located between the fingers to allow them to move laterally to accept the prong (compare figures 4a and 4b). The V-shaped opening defines a first angle that is smaller than angle of the prong when the prong is unattached and the V-shaped opening is adapted to enlarge to the angle of the prong when it is placed in the opening. (Compare figures 4a and 4b and note how the inner fingers (27), which define the V-shaped opening, move outward when the prong is inserted, thus increasing the space between the fingers to accommodate the prong and thereby increasing the angle of the V-shaped opening. The mounting region of the prong is clearly larger than the opening defined by the fingers when unattached and the fingers are movable to form a larger opening when attached (as seen in comparing Fig. 4a and 4b). It is clear by the outward movement of the fingers when the prong is inserted that the fingers (holder) applies a force on the sides of the mounting region of the prong.



5. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the connecting technique of Erhfeld into the stent of Frantzen for the purpose of providing a more secure fit. The bias arms combined with the ratchet teeth would provide a strong hold and prevent the two parts from coming apart. If a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, applying the technique to a similar device would have been obvious.

6. Claims 8-15, 17, 18, 21 and 43-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frantzen in view of Ehrfeld and further in view of Duerig et al (USPN 6,503,271).

7. Frantzen modified by Ehrfeld discloses the device substantially as claimed as stated above except for the limitation that the radiopaque marker is made from a nickel-titanium alloy including a ternary element. However, Duerig discloses a stent with radiopaque markers that are made from a nickel-titanium alloy with a ternary element that is platinum (Col 10, lines 15-23). Duerig further discloses that use of a micro-alloy is advantageous to overcome the challenge of galvanic corrosion (Col 4, lines 22-24). It

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would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a micro alloy into the invention of modified Frantzen in order to provide an enhanced material that prevents galvanic corrosion.

8. Regarding claim 10, modified Frantzen by discloses the claimed invention except for the atomic percent of platinum. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide platinum in the percentage of between and including 2.5% and 15%, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch* 617 F.2d 272,205 USPQ 215 (CCPA 1980).

### ***Response to Arguments***

9. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./  
Examiner, Art Unit 3731

/Anh Tuan T. Nguyen/  
Supervisory Patent Examiner, Art Unit 3731  
4/30/09